Cross modality reconciliation for management and reporting of all cancer related clinical research data

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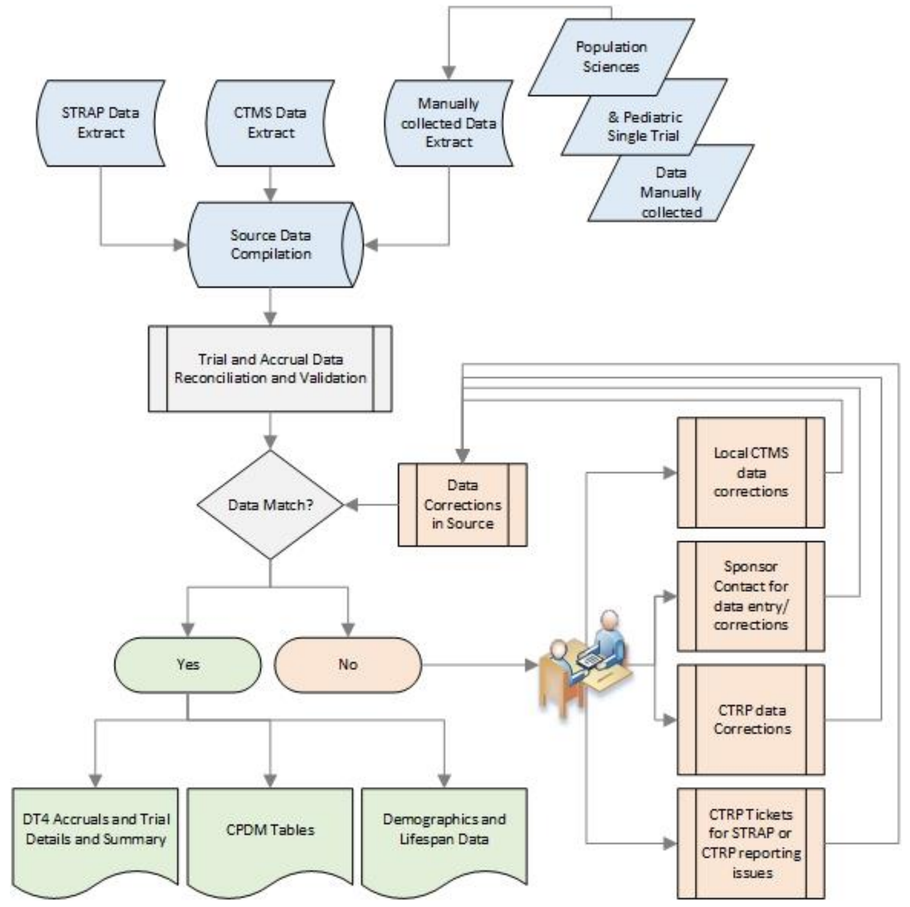
Background:

The University of New Mexico Comprehensive Cancer Center Clinical Research Office has undertaken process improvements to optimize data capture, management, and reporting across all cancer related clinical research driven by the Center sites. The expanded NCI reporting requirements and growth of our community engagement and participation in non-treatment intervention and non-intervention trials required creative solutions to ensure the highest level of data accuracy, and complete data capture. Here we describe the needed process changes and how our innovation and persistence led to significant improvements in data management of all cancer related research.

Goals:

To meet these challenges we aimed to:

- Develop a process to identify and manage data from cancer related clinical research studies performed by Cancer Center Program members.
- Perform comprehensive trial and accrual data reconciliations between all data sources (Clinical Trials Management System (CTMS), Clinical Trials Reporting Program (CTRP) and manual data feeds) quarterly.
- Be prepared to meet upcoming CTRP Non-Interventional trial and accrual registration requirements.
- Broaden operational reporting to include comprehensive demographics for participant accruals where appropriate.



Lessons Learned & Future directions:

- Cross system reconciliation is critical to ensure data accuracy locally and nationally.
- Engagement of clinical leadership was invaluable to ensure we remained aligned with CCSG reporting needs and clinical data accuracy always maintained.
- Leadership review of improved data capture is used to evaluate trail fit and impact within the catchment area.
- We plan to:
  - Develop automated feeds of manual data into our CTMS as needed
  - Automate all CCSG reporting using new visualization / analytics software.
  - Apply lessons learned to newly developing Population Sciences Clinical Working Group.

Solutions:

- For active trials not housed in our CTMS (Velos), we coordinated with Cancer Center Program leaders to manually collect trial and accrual data quarterly from each member. This was expanded beyond trial and accrual data to include composite demographic data per trial.
- We performed direct comparisons of CTRP/STRAP DT4 reports with hybrid DT4 report (CTMS and manual data) and did categorical comparisons to ID discrepancies across all DT4 fields.
- We facilitated reconciliation meetings with Quality Assurance and Operations Managers to review all discrepancies and ensure accuracy of proposed data corrections.
- Data discrepancies within the composite report (CTMS, CTRP, CTEP and Sponsor), were resolved and new Population Sciences Interventional trials were registered in CTRP.
- Data was compiled in formats used for CCSG progress reports and submissions (DT4, Clinical Protocol Data Management (CPDM)), with newly developed minority accrual monitoring templates.

Outcomes:

- Field by field comparisons identified the need for a great deal of data clean up across systems, which now happens in real time as part of our reconciliation process.
- With our collaborative engagement of Population Sciences PIs and Program Leaders, we can now ensure accurate data reporting.
- We now track trials categorically across all Cancer Center Member's departments in accordance with NCI guidelines.
- Newly developed comprehensive demographics tables are now used to monitor minority accruals spanning all Cancer Center member research.